

In the United States Court of Federal Claims

No. 15-1380V

Filed under seal: July 31, 2023

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NOT FOR PUBLICATION

**ANSEL WALTERS and SHAKIMA
DAVIS-WALTERS, Natural Parents of
K.S.S.W., a minor,**

Petitioners,

v.

**SECRETARY OF HEALTH AND
HUMAN SERVICES,**

Respondent.

Phyllis Widman, Widman Law Firm, LLC, Linwood, NJ, for the petitioners.

Sarah B. Rifkin, Torts Branch, Civil Division, U.S. Department of Justice, Washington, DC, for the respondent.

MEMORANDUM OPINION AND ORDER

HERTLING, Judge

The petitioners, Ansel Walters and Shakima Davis-Walters, seek review of a special master's decision denying their claim under the National Vaccine Injury Compensation Program ("Vaccine Program"), 42 U.S.C. § 300aa *et seq.* On behalf of their minor son, K.S.S.W., the petitioners alleged that K.S.S.W. experienced a seizure disorder, encephalopathy, cortical visual impairment, and developmental delays caused by the diphtheria, tetanus, acellular pertussis ("DTaP") vaccine he received on January 16, 2013. The special master denied the petitioners' entitlement to compensation, and the petitioners seek review of that decision.

The petitioners argue that the special master inappropriately assessed the experts' credibility, arbitrarily and capriciously rejected the petitioners' medical theory, and improperly

* Pursuant to Vaccine Rule 18(b), the Court initially filed this opinion under seal and afforded the parties 14 days to notify the court of any information that should be redacted from the opinion for reasons of privilege or confidentiality. The parties did not propose any redactions. Accordingly, this opinion is reissued in its original form for public availability.

raised their burden of proof. The petitioners, however, mischaracterize the special master's opinion and do not assert an adequate basis for remanding the case or reversing the decision under the applicable standard of review. Accordingly, the petitioners' motion for review is denied.

I. FACTUAL BACKGROUND¹

A. K.S.S.W.'s Birth and Pre-Existing Health Conditions

Prenatal ultrasounds on K.S.S.W. indicated that he was likely to be born with ventriculomegaly,² spina bifida,³ and a tethered spinal cord.⁴ (ECF 153 at 4-5.) Prenatal genetic testing revealed that K.S.S.W. had unbalanced chromosomal translocation; chromosome 5p15 was duplicated, and chromosome 6q26 was deleted. (*Id.*) A pediatric geneticist advised the petitioners that K.S.S.W.'s chromosomal arrangement was rare and could result in "malformed brain, mental retardation, and seizures," among other conditions. (*Id.* at 5 (quoting Ex. 4 at 16).) A prenatal specialist advised K.S.S.W.'s mother that his chromosomal abnormalities "were 'likely to result in significant phenotypic abnormalities including neurologic abnormalities, developmental delay, mental retardation, among others.'" (ECF 153 at 5 (quoting Ex. 5 at 86).) Although K.S.S.W.'s mother also has a translocation of the 5p and 6q chromosomes, her

¹ In her opinion, the special master noted: "there is no factual issue regarding the events and circumstances of K.S.S.W.'s medical history which requires adjudication." (ECF 153 at 3.) In their motion for review, the petitioners have not raised any objection to the facts set forth in the special master's entitlement decision. Accordingly, this recitation of the factual background relies on that decision in summarizing the relevant background. The special master's internal citations are omitted. For a full recitation of the facts, see the special master's decision at *Walters v. Secretary of Health & Human Services*, Case No. 15-1380V, 2023 WL 3750716 (Fed. Cl. Spec. Mstr. Apr. 18, 2023).

² Ventriculomegaly is "the gross enlargement of a ventricle of the brain, as by hydrocephalus." (ECF 153 at 4 n.6 (quoting *Dorland's Illustrated Medical Dictionary* 2048 (32d ed. 2012) (hereinafter *Dorland's*)). See also *infra* n.6 (defining hydrocephalus).

³ Spina bifida is "a neural tube defect characterized by defective closure of the vertebral arch, through which the spinal cord and meninges may be protruded." (ECF 153 at 4 n.8 (quoting *Dorland's* 1748).)

⁴ "Tethered spinal cord syndrome (TSCS) is a disorder of the nervous system caused by tissue that attaches itself to the spinal cord and limits the movement of the spinal cord." Tethered Spinal Cord Syndrome, *National Institutes of Health*, <https://www.ninds.nih.gov/health-information/disorders/tethered-spinal-cord-syndrome> (last visited July 27, 2023).

translocation is balanced, so she does not have any disorders resulting from the translocation.⁵ (See ECF 153 at 43.)

K.S.S.W. was born on September 12, 2012, weighing 7 pounds 2 ounces. (*Id.* at 5.) He was transferred to the neonatal intensive care unit and diagnosed with “ventriculomegaly, partial trisomy 5p and monosomy 6q chromosomal abnormalities, spina bifida occulta, and tethered cord syndrome.” (*Id.* at 6.) He was also born with hydrocephalus and underwent ventriculo-peritoneal shunt placement surgery as treatment.⁶ On September 27, 2012, K.S.S.W. was seen by a pediatric neurologist, who “noted that, given the rarity of K.S.S.W.’s genetic abnormality, ‘it is important for us to follow him over time and unclear what his developmental prognosis is.’” (*Id.* at 6 (quoting Ex. 31 at 2) (cleaned up).)

K.S.S.W. received his first doses of the DTaP and three other vaccines on November 26, 2012. No adverse reaction was reported. (ECF 153 at 6.)

K.S.S.W.’s mother testified at the entitlement hearing that prior to his vaccination on January 16, 2013, K.S.S.W. would respond to stimuli, coo, and move his eyes. (*Id.* at 13.) A video of K.S.S.W. shown at the entitlement hearing and at oral argument appears to confirm K.S.S.W.’s mother’s testimony.

B. Vaccination and Seizures

On January 10, 2013, K.S.S.W. was seen by a pediatric neurosurgeon to discuss surgical treatment for his tethered cord syndrome and other vertebral issues. (*Id.* at 7.) On January 16, 2013, K.S.S.W. visited his pediatrician for a pre-surgical evaluation. During this visit to the pediatrician, K.S.S.W. received a second DTaP vaccine. The petitioners alleged that this second DTaP vaccine caused the alleged injuries in this case. (*Id.*)

Four days after K.S.S.W. received his second DTaP vaccine, on January 20, 2013, the petitioners brought K.S.S.W. to the emergency room, reporting intermittent episodes of staring

⁵ The respondent’s expert explained that, unlike K.S.S.W., his mother has “‘the normal complement of genetic information’” and “‘two copies of every gene.’” (ECF 153 at 43 (quoting the transcript).)

⁶ Hydrocephalus is “‘a condition marked by dilatation of the cerebral ventricles, most often occurring secondary to obstruction of the cerebrospinal fluid pathways . . . and accompanied by an accumulation of cerebrospinal fluid within the skull; the fluid is usually under increased pressure, but occasionally may be normal or nearly so.’” (ECF 153 at 5 n.12 (quoting *Dorland’s* 877).)

“A ventriculoperitoneal (VP) shunt is a cerebral shunt that drains excess cerebrospinal fluid (CSF) when there is an obstruction in the normal outflow or there is a decreased absorption of the fluid.” Ventriculoperitoneal Shunt, *National Institutes of Health*, <https://www.ncbi.nlm.nih.gov/books/NBK459351/> (last visited July 11, 2023).

off to the left since January 17, 2013. (*Id.*) At oral argument, the petitioners showed a video taken on January 20, 2013, of K.S.S.W.'s eyes going blank and of his unresponsiveness to his mother's voice. The petitioners had sent a video of K.S.S.W. to the pediatric neurosurgeon, who advised them to bring K.S.S.W. to the emergency room immediately.⁷ (*Id.*)

The hospital performed a computerized tomography ("CT") scan of K.S.S.W.'s head and admitted K.S.S.W. for seizures. (*Id.*) His emergency-room records reflect that K.S.S.W. did not have a fever and was not vomiting at the time he was admitted; he experienced some vomiting a few days later. (*Id.* at 7-8.) After reviewing K.S.S.W.'s CT scan, bloodwork, and magnetic resonance imaging tests, a neurologist diagnosed K.S.S.W. with multifocal epilepsy, "'most likely related to the underlying hydrocephalus and brain malformation.'" (*Id.* at 8 (quoting Ex. 7 at 629).) Electroencephalogram ("EEG") monitoring of K.S.S.W. showed frequent epileptic spikes. (ECF 153 at 8.)

The neurologist "observed that K.S.S.W. had several seizure episodes which were accompanied by eye deviations, other instances when his parents pressed a button indicating a seizure was occurring without any EEG correlation, and occasions when they ignored electrographic seizures without any clinical presentation, even when holding K.S.S.W." (*Id.*) The neurologist explained that "'because we are seeing EEG seizures without any clinical symptoms, they may have been occurring previously and there was no way to know that seizures were occurring until he had a big enough one to cause physical symptoms.'" (*Id.* (quoting Ex. 7 at 629).) K.S.S.W. was given several different antiepileptic medications and discharged in stable condition on February 5, 2013. (ECF 153 at 9.)

K.S.S.W. was re-admitted to the hospital twice in February of 2013—on February 7 and on February 27. (*Id.*) EEG monitoring continued to show epileptic activity, and K.S.S.W.'s dosages of antiepileptic medication were adjusted. (*Id.*)

K.S.S.W. continued to see other medical specialists, including a cardiologist and ophthalmologist. (*Id.*) The ophthalmologist theorized that K.S.S.W. had possible neurologic blindness. (*Id.*) K.S.S.W. received tethered cord surgery on April 12, 2013, and there were no related complications. (*Id.*)

K.S.S.W. was hospitalized again for a prolonged seizure in June 2013. (*Id.*) In July 2013, K.S.S.W. had a follow-up appointment with his neurologist, who noted that K.S.S.W. had experienced only one seizure since his hospitalization in June. (*Id.* at 10.) K.S.S.W. was attending regular physical and occupational therapy, eating solid food, and taking his bottle without problems. (*Id.*) At K.S.S.W.'s next appointment with his neurologist in September 2013, the neurologist noted that K.S.S.W. had experienced difficulties tolerating some of his antiepileptic medication, and that EEG monitoring continued to show some seizure activity. (*Id.*) At that time, the one-year-old K.S.S.W. still could not sit without support and could not bear

⁷ It is unclear from the record and the special master's opinion which video or videos the neurosurgeon reviewed. (See ECF 153 at 7 n.18.)

weight on his legs. (*Id.*) K.S.S.W.’s pediatrician also noted K.S.S.W.’s global developmental delays. (*Id.*)

C. Medical History After K.S.S.W.’s First Year of Life

K.S.S.W. continued to see a pediatrician, neurologist, and ophthalmologist regularly. (*Id.* at 10-11.) His most recent ophthalmologist has diagnosed him with cortical visual impairment secondary to his congenital hydrocephalus. (*Id.* at 11-12.) K.S.S.W. still experiences occasional breakthrough seizures. (*Id.* at 12.) Doctors have informed the petitioners that K.S.S.W. is unlikely ever to be able to talk or walk. (*Id.* at 14.) The petitioners still had to carry and feed eight-year-old K.S.S.W. when the special master issued the underlying decision. (*Id.*)

On June 6, 2019, K.S.S.W. and his mother saw K.S.S.W.’s pediatrician to discuss his chromosomal abnormalities. (*Id.* at 12.) The pediatrician and K.S.S.W. discussed the possibility that vaccines may have triggered K.S.S.W.’s seizures. The pediatrician opined that his “‘chromosomal abnormalities could account for his current systems/development, unless mom can give [history]/documentation that seizures started right after a vaccine was given.’” (*Id.* (quoting Ex. 162 at 2) (cleaned up).)

K.S.S.W.’s mother and his pediatrician discussed the connection between vaccines and K.S.S.W.’s seizures again on June 13, 2019. K.S.S.W.’s mother recounted that after K.S.S.W. had received the second DTaP vaccine, his eyes began rolling inward and he would neither eat nor cry. (*Id.* at 12.) She also noted that although she has a similar chromosomal abnormality, she does not suffer from seizures. (*Id.*) The pediatrician wrote that she understood the timeline of the seizures and vaccine and asked if K.S.S.W.’s mother would like to consider future varicella or MMR vaccines. The pediatrician assessed K.S.S.W. with “Vaccines adverse reaction.” (*Id.*)

II. PROCEDURAL HISTORY

The petition for compensation under the Vaccine Program was filed on November 16, 2015. (ECF 1.) The petitioners alleged that the DTaP vaccine had caused K.S.S.W. to suffer Table encephalopathy and seizures.⁸ (*Id.*)

Over the next several years, the parties exchanged affidavits, medical records, expert reports, and medical literature. (*See* ECF 153 at 2.) The special master held an entitlement hearing on January 21 and January 22, 2021. (*Id.* at 2-3.) The petitioners submitted two expert reports from Dr. Yuval Shafrir, a pediatric neurologist and epileptologist, and two expert reports

⁸ In general, “[e]ncephalopathy is described clinically as an alteration in generalized attention, cognition, or consciousness. It is a form of diffuse cerebral dysfunction with varying severities.” Encephalopathic EEG Patterns, National Institute of Health, <https://www.ncbi.nlm.nih.gov/books/NBK564371/> (last visited July 17, 2023). To demonstrate Table encephalopathy, a child younger than 18-months-old must present “a significantly decreased level of consciousness that lasts at least 24 hours.” 42 C.F.R. § 100.3(c)(2)(i).

from Dr. Omid Akbari, a professor of immunology. (*Id.* at 17.) The respondent submitted four expert reports from Dr. Neil Romberg, a pediatric immunologist, and two expert reports from Dr. Kristin Barañano, a pediatric neurologist and neurogeneticist. (*Id.* at 17, 20.) The special master heard testimony from the petitioners, K.S.S.W.’s maternal grandmother, and the parties’ four experts. (*Id.* at 13-15, 20.)

On April 18, 2023, the special master issued a 46-page opinion denying the petitioners’ claims. At the outset of her analysis, the special master found the respondents’ experts more persuasive than the petitioners’ experts. “At important junctures, both Dr. Shafrir and Dr. Akbari substantially misstated or ignored significant aspects of K.S.S.W.’s symptoms, condition, and care.” (*Id.* at 30.) Additionally, “Dr. Shafrir and Dr. Akbari repeatedly overstated K.S.S.W.’s prior abilities, exaggerated his condition post-vaccination, and confused specific timing and facts.” (*Id.* at 30-31.) The special master also noted that Dr. Akbari was not a medical doctor and appeared to employ medical terms interchangeably by mistake. (*Id.* at 32.) He also “ventured outside his area of expertise and offered his opinions on the import of certain findings from K.S.S.W.’s bloodwork, and the specifics of K.S.S.W.’s genetic anomaly, areas better left to medical doctors and providers with expertise in neurogenetics, respectively.” (*Id.*)

The special master noted that the petitioners were unable to satisfy the requirements for Table encephalopathy—a fact they appeared to acknowledge by expending little time asserting that claim.⁹ (*Id.* at 33.)

The special master proceeded to analyze whether the petitioners had demonstrated that the DTaP vaccine caused K.S.S.W.’s seizures under the three-prong test established in *Althen v. Secretary of Health and Human Services*, 418 F.3d 1274, 1278 (Fed. Cir. 2005). Under that test, a petitioner must set forth by preponderant evidence: “(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury.” *Id.*

The special master found that under the first *Althen* prong the petitioners had not proposed a plausible medical theory that the DTaP vaccine *could* cause afebrile seizures like the ones K.S.S.W. experienced. The petitioners’ proposed medical theories of immune dysregulation and molecular mimicry were unpersuasive and had been discredited in similar cases. (ECF 153 at 36-40.)

Under the second *Althen* prong, the special master held that the petitioners had “failed to provide a logical sequence of cause and effect showing the DTaP vaccine *did cause* K.S.S.W.’s afebrile seizures, developmental delays, and [cortical visual impairment], as alleged.” (*Id.* at 40 (emphasis in original).) There was no medical evidence that K.S.S.W. experienced an inflammatory response to the second DTaP vaccination, and K.S.S.W.’s treating physicians

⁹ At oral argument, the petitioners confirmed that they do not seek review of the dismissal of their Table claim.

attributed his seizures to his chromosomal abnormalities, not to any autoimmune condition. (*Id.* at 41-42.) Both of K.S.S.W.’s chromosomal abnormalities carry a 30-50 percent risk of seizures; the respondent’s experts posited that the rare combination of those chromosomal abnormalities would create an additive risk. (*Id.* at 43-44.)

Under the third *Althen* prong, the special master noted that the petitioners failed to demonstrate the requisite proximate temporal relationship in K.S.S.W.’s case. (*Id.* at 45.) Accordingly, the special master determined that the petitioners had failed to demonstrate that the DTap vaccine caused K.S.S.W.’s injuries, and their claims were dismissed. (*Id.*)

The petitioners filed a timely motion for review of the special master’s decision. (ECF 156.) The respondent filed a response. (ECF 159.) The case was reassigned to the undersigned on July 5, 2023. (ECF 161.) Oral argument was held on July 25, 2023.

III. JURISDICTION AND STANDARD OF REVIEW

The Court of Federal Claims has jurisdiction to review the decisions of special masters under the Vaccine Program. 42 U.S.C. § 300aa-12(e). Pursuant to this jurisdiction, the court may “set aside any findings of fact or conclusion of law of the special master found to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law and issue its own findings of fact and conclusions of law.” 42 U.S.C. § 300aa-12(e)(2)(B); *see also* Rule 27(b), Appendix B to the Rules of the Court of Federal Claims (“RCFC”).

The Federal Circuit has described the standard of review to be applied to the court’s review of a decision by a special master as “the most deferential possible.” *Munn v. Sec’y of Dep’t of Health & Hum. Servs.*, 970 F.2d 863, 870 (Fed. Cir. 1992). A court “owes [the] findings and conclusions by the special master great deference—no change may be made absent first a determination that the special master was ‘arbitrary and capricious.’” *Id.* The degree of deference depends on which aspect of the special master’s judgment is under review. *Id.* at 870 n.10. A court “may set aside the decision of a special master only if the special master’s fact findings are arbitrary and capricious, its legal conclusions are not in accordance with law, or its discretionary rulings are an abuse of discretion.” *Turner v. Sec’y of Health & Hum. Servs.*, 268 F.3d 1334, 1337 (Fed. Cir. 2001).

IV. DISCUSSION

In their motion for review of the special master’s decision, the petitioners assert three grounds for reversal. First, the petitioners argue that the special master abused her discretion by discrediting their experts. Second, the petitioners argue that the denial of their claims was arbitrary and capricious because K.S.S.W.’s chromosomal abnormalities likely affected his immune response to vaccination, and the petitioners had provided adequate evidence of a reputable medical theory and a temporal relationship between the vaccination and the alleged injuries. Third, the petitioners argue that the special master improperly heightened the petitioners’ burden of proof.

A. The Credibility Determination

In general, “[w]eighing the persuasiveness of particular evidence often requires a finder of fact to assess the reliability of testimony, including expert testimony, and [the Federal Circuit has] made clear that the special masters have that responsibility in Vaccine Act cases.” *Moberly ex rel. Moberly v. Sec’y of Health & Hum. Servs.*, 592 F.3d 1315, 1325 (Fed. Cir. 2010). Special masters “are entitled—indeed, expected—to make determinations as to the reliability of the evidence presented to them and, if appropriate, as to the credibility of the persons presenting that evidence.” *Id.* at 1326.

Special masters have “broad discretion in determining credibility because [they] saw the witnesses and heard the testimony.” *Bradley v. Sec’y of Dep’t of Health & Hum. Servs.*, 991 F.2d 1570, 1575 (Fed. Cir. 1993). Accordingly, their credibility determinations are “‘virtually unreviewable.’” *Id.* (quoting *Hambusch v. Dep’t of Treasury*, 796 F.2d 430, 436 (Fed. Cir. 1986)). The broad discretion afforded to special masters does not, however, permit them to “cloak the application of an erroneous legal standard in the guise of a credibility determination, and thereby shield it from appellate review.” *Andreu ex rel. Andreu v. Sec’y of Dep’t of Health & Hum. Servs.*, 569 F.3d 1367, 1379 (Fed. Cir. 2009). A credibility determination should serve “to assess the candor of a fact witness, not to evaluate whether an expert witness’ medical theory is supported by the weight of epidemiological evidence.” *Id.*

The petitioners argue that the special master abused her discretion by affording more weight to the respondent’s experts than to the petitioners’ experts. (*See* ECF 156-1 at 13-17.) The petitioners argue that the special master’s opinion contravenes *Andreu*; they object to a footnote in the special master’s opinion noting that because Dr. Barañano was the only expert with expertise in neurogenetics, her testimony in that area was given more weight. The petitioners argue that Dr. Shafrir and Dr. Akbari were better qualified to testify about the cause of K.S.S.W.’s health problems than Dr. Barañano and Dr. Romberg: Dr. Shafrir was the only expert in epileptology, and Dr. Akbari’s research on dysregulated immune responses to immunization supported the petitioners’ medical theory. The petitioners argue that Dr. Barañano merely has a year-long fellowship in neurogenetics, cannot read EEG scans without the help of other clinicians, and struggled during cross-examination to articulate the causal mechanism of Table encephalopathy, which has broad medical and legal acceptance. The petitioners also point out that, like Dr. Akbari, Dr. Romberg also focuses more on research than on clinical practice.

The petitioners mischaracterize the reasons for the special master’s credibility determinations. The special master recognized Dr. Shafrir as an expert in neurology and epileptology and recognized Dr. Akbari as an expert in immunology, noting their numerous awards, honors, and publications. (ECF 153 at 17-19.) The special master nonetheless found them less persuasive than the respondent’s experts not due to their lack of qualifications but for other reasons—namely, that their descriptions of the timing and symptoms of K.S.S.W.’s conditions contradicted contemporaneous medical records. The special master listed incidences of those inaccuracies, including the overstatement of K.S.S.W.’s abilities pre-vaccination, discrepancies with the timing of the onset of K.S.S.W.’s seizures, and assertions of symptoms K.S.S.W. did not experience. (*Id.* at 30-32.) Additionally, the special master found the petitioners’ experts less persuasive when they offered testimony outside of their areas of

expertise. (*Id.* at 32.) In the footnote raised by the petitioners, the special master noted that “*in areas of neurogenetics*,” Dr. Barañano’s testimony was given more weight than the testimony of the petitioners’ experts. (*Id.* at 43 n.51 (emphasis added).)

The special master’s weighing of the expert testimony complies with *Andreu*, 569 F.3d at 1379. The special master made a credibility determination to assess the experts’ “candor” regarding K.S.S.W.’s health conditions and the likely cause of those conditions; she did not “cloak the application of an erroneous legal standard in the guise of a credibility determination.” *See id.* The special master did not abuse her “broad discretion” by discounting testimony offered outside of an expert’s area of expertise and crediting testimony that an expert was uniquely qualified to offer. *See Bradley*, 991 F.2d at 1575.

Additionally, the petitioners’ attempts to diminish the qualifications of the respondent’s experts lack foundation. In addition to her fellowship in neurogenetics, Dr. Barañano “teaches medical students, residents, and fellows in genetics” and “has published 25 peer-reviewed articles regarding pediatric neurology and neurogenetics.” (ECF 153 at 20, 43 n.51.) Her supposed inability to interpret EEG scans on her own and her testimony regarding Table encephalopathy are irrelevant when the special master did not rely on Dr. Barañano’s testimony for those issues. In addition, Dr. Romberg’s pediatric residency gives him more clinical experience than Dr. Akbari has, even though both experts currently focus primarily on research rather than clinical practice.

Even if the petitioners had succeeded in their argument that their experts were better qualified than those of the respondent, precedents from the Federal Circuit put a thumb on the scale for a special master’s initial credibility determination. The special master “saw the witnesses and heard the testimony,” and her judgment as to the credibility of the testimony is thus afforded broad deference. *See Bradley*, 991 F.2d at 1575. She did not abuse her discretion by finding the respondent’s experts more credible when their testimony aligned more accurately with contemporaneous medical records, and they did not venture outside their areas of expertise. Accordingly, the special master’s “virtually unreviewable” credibility determination should not be disturbed. *See id.* (quoting *Hambsch*, 796 F.2d at 436).

B. Whether the Special Master’s Decision Was Arbitrary and Capricious

The petitioners argue that the special master’s decision was arbitrary and capricious because she required the petitioners to produce “conclusive evidence that K.S.S.W.’s unbalanced genetic translocation had an effect on his immune response to vaccination” in medical literature despite the rarity of K.S.S.W.’s genetic conditions. (ECF 156-1 at 18.) The petitioners note that K.S.S.W.’s “particular combination of abnormalities has only been reported once in medical literature.” (*Id.* at 10.) The petitioners also argue that they provided adequate evidence of a reputable medical theory of causation. Additionally, they object to the special master’s analysis of the temporal relationship between K.S.S.W.’s vaccination and the onset of his alleged injuries.

1. Whether Conclusive Evidence Was Required

The petitioners mischaracterize the special master's opinion. The special master repeatedly acknowledged the rarity of K.S.S.W.'s genetic conditions (ECF 153 at 5, 6, 44) and noted that the "[p]etitioners may satisfy the first *Althen* prong without resort to medical literature, epidemiological studies, demonstration of a specific mechanism, or a generally accepted medical theory." (ECF 153 at 34 (citing *Andreu*, 569 F.3d at 1378-79.) She also acknowledged that the petitioners were "not required to describe the exact mechanism of causation." (ECF 153 at 34 (citing *Knudsen v. Sec'y of Health & Hum. Servs.*, 35 F.3d 543, 549 (Fed. Cir. 1994).)

The petitioners nonetheless bear the burden of showing that it was "more likely than not" that the DTaP vaccine could cause K.S.S.W.'s injuries. *Moberly*, 592 F.3d at 1322. Moreover, "to say that proof in the form of epidemiological studies or well-established medical experience is not mandatory does not mean that the special masters in Vaccine Act cases are precluded from inquiring into the reliability of testimony from expert witnesses." *Id.* at 1325. To prove non-Table injuries, a petitioner must prove "by a preponderance of the evidence, that the vaccine was not only a but-for cause of the injury but also a substantial factor in bringing about the injury." *Shyface v. Sec'y of Health & Hum. Servs.*, 165 F.3d 1344, 1352 (Fed. Cir. 1999).

The special master considered and evaluated in detail the medical theories advanced by both parties. Because of the rarity of K.S.S.W.'s genetic conditions, both parties' medical theories of causation required a degree of speculation. Nonetheless, the special master found the petitioners' theory unpersuasive. In particular, "Dr. Akbari's opinion [was] based on a misunderstanding of K.S.S.W.'s chromosomal array and the consequences associated with his chromosomal duplication and deletion." (ECF 153 at 37.) Dr. Akbari had apparently misapprehended the location of K.S.S.W.'s duplicated gene and the location of K.S.S.W.'s deleted gene. (*See id.* at 37-38.) The studies proffered by Dr. Shafrir involved vaccines not administered to K.S.S.W. and symptoms absent from K.S.S.W.'s case. (*Id.* at 39-40.) Some of the medical literature put forth by the petitioners had also been rejected in other cases. (*Id.* at 40.) By contrast, the special master accepted the respondent's theory that K.S.S.W.'s chromosomal abnormalities alone were more likely than not to have caused the seizures he experienced. (*Id.* at 44.) The special master's finding in this respect is supported by medical literature and the opinions of K.S.S.W.'s treating physicians.

Nowhere in her opinion did the special master require "conclusive evidence" that K.S.S.W.'s genetic condition caused an immune reaction to the vaccine. (*See* ECF 156-1 at 18.) Rather, after considering all the relevant evidence, the special master concluded that it was "more likely than not" that the vaccine was not a "substantial factor" causing K.S.S.W.'s health conditions. *See Moberly*, 592 F.3d at 1322; *Shyface*, 165 F.3d at 1352. The special master was not precluded from inquiring into the accuracy and reliability of the expert witnesses' testimony to reach an opposite conclusion from that of the petitioners' experts.

2. Whether the Petitioners Advanced an Adequate Medical Theory

In their motion for review, the petitioners reassert their theory that the absence of the CCR6 molecule from K.S.S.W.'s sixth chromosome caused his adverse reaction to the vaccine:

CCR6 recruits the T Regulatory cells (Tregs) which help mediate immune responses in the body. [] CCR6 is directly involved in trafficking, and in the functionality of, Tregs. [] Without CCR6, these mechanisms are impaired. [] This is clear, unequivocal evidence that K.S.S.W.'s immune system was more likely than not unprepared to handle an immune reaction, such as one to a vaccination. The mechanism of causation is exactly the same as that accepted on the table, K.S.S.W.'s genetic abnormalities merely primed him for his adverse reaction, as explained from both a neurology and immunology perspective by Petitioner's experts.

(ECF 156-1 at 19-20 (internal citations omitted).) The petitioners argue that the same causal mechanism at issue for Table encephalopathy applies to their case; because of K.S.S.W.'s dysregulated immune system, however, his symptoms do not perfectly align with those associated with the Table injury.

The special master considered the petitioners' theory but found it unpersuasive because of the testimony of the respondent's expert:

Dr. Romberg's additional point that losing one copy of CCR6 does not affect Treg function is [] persuasive. Specifically, he testified that loss of CCR6 more likely protects against neuroinflammation than the converse. [] As Dr. Romberg described in his second expert report, "CCR6 is a chemokine receptor expressed by all proinflammatory Th17 lineage cells. The receptor allows Th17 cells to traffic to mucosal sites of inflammation." [] He went on to note that the impaired trafficking of Th17 cells "would reduce, not increase, their ability to participate in inflammatory responses." [] This position is supported by the Chen paper, which found that reduction of CCR6 expression blocks Th17 trafficking to the brain in a murine model. [] Further, the Reboldi paper demonstrates that CCR6 deficient mice are resistant to autoimmune encephalitis.

(ECF 153 at 39 (internal citations omitted).)

A reviewing court in a vaccine case should not "reweigh the factual evidence, assess whether the special master correctly evaluated the evidence, or examine the probative value of the evidence or the credibility of the witnesses—these are all matters within the purview of the fact finder." *Porter v. Sec'y of Health & Hum. Servs.*, 663 F.3d 1242, 1249 (Fed. Cir. 2011). When the "special master's decision reveals a thorough and careful evaluation of all of the evidence including records, tests, reports, and medical literature, as well as the experts' opinions

and their credibility,” the decision should not be disturbed. *Id.* at 1254. Additionally, the Federal Circuit has held that the “similarity of a petitioner’s injury to those listed on the Table does not show causation in fact.” *Grant v. Sec’y of Health & Hum. Servs.*, 956 F.2d 1144, 1148 (Fed. Cir. 1992). To prove a Table injury, a petitioner must show the exact symptoms provided in the Table because “[e]ncephalitis, seizure disorders, and the other Table injuries can have causes other than the administration of a vaccine.” *Id.*

The petitioners do not engage with the special master’s decision rejecting their theory, let alone explain why her logic is incorrect. The special master considered the petitioners’ proffered medical theory and explained why it appeared to be highly unlikely, much less supported by preponderant evidence. The special master did so in reliance on credible expert testimony and medical literature. At this stage of the litigation, it would be inappropriate to reweigh the evidence considered and reassess the reliability of Dr. Romberg’s and Dr. Akbari’s testimony and reports. *See Porter*, 663 F.3d at 1249, 1254. Additionally, the appearance of encephalopathy on the Table does not satisfy the petitioners’ burden when K.S.S.W.’s symptoms did not correspond to those of Table encephalopathy. *See Grant*, 956 F.2d at 1148. The special master’s decision that the petitioners had not advanced an adequate medical theory therefore was not arbitrary and capricious.

3. The Special Master’s Temporal Relationship Analysis

The petitioners argue that the special master’s analysis of the temporal relationship between K.S.S.W.’s vaccine and the alleged injuries was arbitrary and capricious. The petitioners assert that the special master’s analysis was brief and erroneously focused on whether the petitioners had “provide[d] a reliable theory for how the DTaP vaccine could cause afebrile seizures, developmental delay, and [cortical visual impairment.]” (*See* ECF 153 at 45.)

In *W.C. v. Secretary of Health and Human Services*, the Federal Circuit held that because petitioners must establish all three prongs of the *Althen* test, a petitioner’s failure to prove one of the prongs obviates the need for the special master to analyze a petitioner’s claims under the other *Althen* prongs. 704 F.3d 1352, 1358 (Fed. Cir. 2013).

Accordingly, the special master did not need to engage in any analysis of the third *Althen* prong after dismissing the petitioners’ claims on the first two *Althen* prongs. The special master’s analysis of the temporal relationship challenged by the petitioners is not central to her holding. Even if the petitioners’ challenge on this issue is correct, the result would not change. Accordingly, the Court declines to address this argument, and the petitioners’ challenge fails.

C. The Application of the Burden of Proof

Finally, the petitioners argue that the special master “expected Petitioner[s] to disprove Respondent’s theory that K.S.S.W.’s genetic abnormalities were the sole cause of his epileptic issues and denied compensation largely because she believed Petitioner did not meet this heightened burden.” (ECF 156-1 at 21.) The petitioners argue that K.S.S.W.’s chromosomal abnormalities alone did not definitively predestine him for seizures and that the special master erroneously forced the petitioners to disprove the respondent’s suggested medical theories.

A petition in the Vaccine Program may only be granted if “the petitioner has demonstrated by a preponderance of the evidence the matters required in the petition by section 300aa-11(c)(1) of this title, *and* [] there is not a preponderance of the evidence that the illness, disability, injury, condition, or death described in the petition is due to factors unrelated to the administration of the vaccine described in the petition.” 42 U.S.C. § 300aa-13(a)(1) (emphasis added).

To establish a “prima facie case,” a petitioner has the burden of demonstrating that “the person received a vaccine set forth in the Vaccine Injury Table and sustained an illness, disability, injury, or condition caused by that vaccine.” *Doe v. Sec’y of Health & Hum. Servs.*, 601 F.3d 1349, 1357 (Fed. Cir. 2010). Once a petitioner establishes a prima facie case, the burden shifts to the respondent to prove that the injury or death was caused by a factor unrelated to the vaccine. *Id.*

A special master cannot “*require* the petitioner to *eliminate* alternative causes as part of establishing its prima facie case.” *Id.* at 357-58 (emphases added). A special master can, however, consider alternative causes as a factor in deciding whether petitioners have met their burden to establish a prima facie case. *See Sharpe v. Sec’y of Health & Hum. Servs.*, 964 F.3d 1072, 1082 (Fed. Cir. 2020) (“[A] court should consider all evidence in the record, including evidence of other possible sources of injury.”) “Indeed, in some cases a sensible assessment of causation cannot be made while ignoring the elephant in the room—the presence of compelling evidence of a different cause for the injury in question.” *Stone v. Sec’y of Health & Hum. Servs.*, 676 F.3d 1373, 1380 (Fed. Cir. 2012). A special master does not commit legal error by considering an alternative cause as “just one factor among many” in rejecting a petitioner’s theory of causation. *Doe*, 601 F.3d at 1349.

The Vaccine Act requires the special master to have considered whether something other than the DTaP vaccine—in this case, K.S.S.W.’s chromosomal abnormalities—caused K.S.S.W.’s seizures or conditions. *See* 42 U.S.C. § 300aa-13(a)(1). The petitioners had the burden of proof to establish that the vaccine was more likely than not to have caused K.S.S.W.’s seizures. *See Doe*, 601 F.3d at 1357.

The special master did not “require the petitioner[s] to eliminate” K.S.S.W.’s genetic condition as an alternative cause of K.S.S.W.’s seizures. *See id.* at 1357-58. Rather, the special master carefully considered the entirety of the evidence in the record, including K.S.S.W.’s voluminous medical records involving his treatments for congenital health conditions. K.S.S.W.’s genetic mutations were the proverbial “elephant in the room”—his treating physicians attributed his health problems to his genetic conditions, and both parties’ experts discussed K.S.S.W.’s genetic conditions in detail. *See Stone*, 676 F.3d at 1380. Given the evidence in the record and the expert testimony on the subject, the special master properly considered K.S.S.W.’s genetic conditions as an alternative cause of his injuries. *See Doe*, 601 F.3d at 1358.

Additionally, the special master considered the alternative cause as “just one factor among many” in concluding that the vaccine likely did not cause K.S.S.W.’s conditions. *See id.* Those other factors included the low likelihood that the DTaP vaccine would trigger an afebrile

seizure, the petitioners' misapprehension of the location of K.S.S.W.'s genetic abnormalities, medical literature discrediting the petitioners' theory, the limited support in the medical literature for the petitioners' position, the fact that K.S.S.W.'s medical records did not comport with the petitioners' medical theory, and the opinions of K.S.S.W.'s treating physicians. (ECF 153 at 37-43.)

An examination of the record and the special master's thorough consideration of the evidence in the record discloses that the special master's consideration of K.S.S.W.'s genetic abnormalities was just one of several reasons for the special master's conclusion that the petitioners had not established causation-in-fact. The special master neither heightened the petitioners' burden of proof nor erred by considering potential alternative causes for K.S.S.W.'s seizures as a factor in her analysis.

V. CONCLUSION

The special master appropriately assessed the experts' credibility. Her rejection of the petitioners' medical theory was not arbitrary and capricious, and she applied the appropriate burdens of proof and legal standards. Accordingly, the special master's decision is sustained, and the petitioners' motion for review (ECF 156) is **DENIED**. The Clerk is **DIRECTED** to enter judgment for the respondent.

It is so **ORDERED**.

s/ Richard A. Hertling

Richard A. Hertling
Judge